

510(k) Summary of Safety and Effectiveness

K073358

APR 25 2008

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

November 25, 2007

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. K.S. Yun

General Manager

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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name: Lumimed Series 5MP Digital Flat Panel Display System™

Common Name: Picture Archiving Communications System

Device Classification: 892.2050 - LLZ

Name: System, Image Processing

Predicate Device: 21 CFR 807.92(a)(3)

510(k) Number	K031929
Device Classification Name	system, image processing, radiological
Device Name	5MP TFT LCD MONITOR SYSTEM IF2105A
Applicant	WIDE Corporation
Regulation Number	892.2050
Classification Product Code	LLZ
Decision Date	07/08/2003
Decision	substantially equivalent (SE)
Classification Advisory Committee	Radiology

Device Description: 21 CFR 807.92(a)(4)

Lumimed Series 5MP Digital Flat Panel Display System™ is a flat panel hi-resolution LCD monitor system for displaying medical images. The system consists of a state-of-the-art LCD monitor and a high-resolution graphic control board that connects to a PACS workstation for grayscale and color image display. The controller board is installed into the PACS workstation computer or other computer system used to display PACS medical images.

510(k) Summary of Safety and Effectiveness

Indications for Use: 21 CFR 807 92(a)(5)

The Lumimed Series 5MP Digital Flat Panel Display System™ is intended to be used in displaying and viewing digital medical images for review and analysis by trained medical practitioners. It is specifically designed for digital mammography applications.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device is an image display system consisting of computer software and components. The device does not contact the patient, nor does it control any life sustaining devices. A physician or trained medical practitioner provides ample opportunity for competent human intervention to interpret images and information being displayed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for the Lumimed Series 5MP Digital Flat Panel Display System™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The Lumimed Series 5MP Digital Flat Panel Display System™ will be manufactured by HeeYoung Co., Ltd. in accordance with the voluntary and safety standards, i.e. Safety / Immunity UL2601-1/EN60601-1 / IEC601-1, FCC Class B, CE, VCC, UL 950, cUL2601-1, CE Mark EMC/IEC = VCCI, CE, MIC FCC Class B digital device, pursuant to Part 15.

The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

HeeYoung Co., Ltd.
% Mr. Carl Alletto
Consultant
OTech, Inc.
1600 Manchester Way
CORINTH TX 76210

Re: K073358

Trade/Device Name: Lumimed Series 5MP Digital Flat Panel Display System™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 19, 2008
Received: April 22, 2008

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

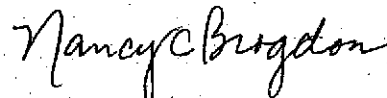
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(Indications for Use Form)

510(k) Number:

Device Name: Lumimed Series 5MP Digital Flat Panel Display System™

Indications for Use:

The Lumimed Series 5MP Digital Flat Panel Display System™ is intended to be used in displaying and viewing digital medical images for review and analysis by trained medical practitioners. It is specifically designed for digital mammography applications.

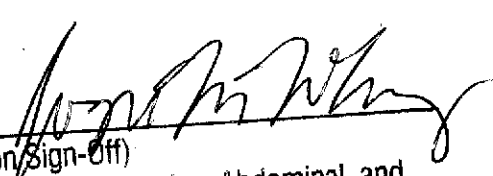
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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)


(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K073358